58. (New) A composition comprising a nucleic acid sequence encoding carcinoembryonic antigen (CEA) and a nucleic acid sequence encoding an amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5.

59. (New) The composition of claim 58, wherein said composition encodes an amino acid sequence which is capable of stimulating a CEA specific cytolytic cytotoxic T lymphocyte (CTL) response in a subject.

REMARKS

Claims 47-56 have been rejected. Applicants have added claims 57-59. Accordingly, claims 47-59 are pending for examination.

Support for amended claim 47 is found on, for example, page 12, lines 1-35 of the specification. This amendment is made to broaden claim 47 and is not made for reasons of patentability. Support for new claim 57 and 59 are found, for example, on page 6, lines 1-35, of the specification. Support for claim 58 is found in numerous places in the specification. For example, on page 4, lines 8-10, the inventors express possession of an invention combining CEA and CAP1, which when read in combination with page 6, lines 1-35, for example, shows the possession of the combination of CEA and the CAP1 agonists of SEQ ID NOs 2-5. The further support for a nucleic acid comprising said combination is shown, for example, on page 7, lines 10-15, which describes "a gene encoding CEA" and, for example, page 20 lines 1-35 and the following page which describe "DNA sequence[s] encoding the peptide agonist." Applicants respectfully submit that the written description law does not require a description in the specification of the exact claim language, as is discussed below. It is permissible under the law for written description to be provided by a (1) a combination of elements in the specification that would be necessarily apparent to the skilled artisan. See *Union Oil v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) (written description was adequately provided by combining different teachings in the specification where the specification did not disclose any embodiments corresponding to any of the claims at issue) (cited in MPEP 2163.06, page 2100-182, 1st col., Rev. 2,

May 2004). Also, (2) written description may be provided by an advantage that is an inherent property of the invention. See MPEP 2163.07(a), page 2100-184, 1st col., Rev. 2, May 2004. The specification , as set forth above, discloses (1) a combination of CEA and the agonist peptide, (2) that CEA may be in the form of a nucleic acid and (3) that the agonist peptide may be in the form of a nucleic acid. Applicants submit that given this explicit disclosure, the skilled artisan necessarily would have recognized that the inventors, at the time of filing, were in possession of the claimed composition. Furthermore, applicants submit that, as evidenced by the explicit disclosure in the specification cited above, the inventors were in possession of an invention having the advantageous property achieved when CEA and an agonist peptide are combined. It would be immediately apparent to the skilled artisan that the inventors were in possession of the discovery of this advantageous combination and that this combination could be in the form of amino acids or in the precursor form of nucleic acids encoding the amino acids.

Response to the Examiners Rejections and Objections

In paragraph 2 of the Office Action, the Examiner notes the election and examination of the species of SEQ ID NO: 2. Applicants respectfully request that upon the finding that SEQ ID NO:2 is clear of the prior art that the Examiner examine SEQ ID NO:s 3-5, as is in conformance with the relevant MPEP guidelines.

In paragraph 3 of the Office Action, the Examiner requests the reference in the specification to the non-provision priority application be updated to show the status of such application. Applicants have amended the specification to do so.

In paragraph 4, the Examiner has stated that the inventors' declaration is defective because the changes to the resident address of Dr. Barzaga are not initialed and dated and the filing date of application serial number 09/529,121 is not given. Applicants submit that a corrected declaration is not required. Under MPEP 602.01, page 600-34, 1st col., Rev. 2, May 2004 and MPEP 601.05, Rev. 2, May 2004, it is stated that the correction of the residence information of an inventor may be made in the application data sheet and need not be corrected in the inventors' declaration. The

inventor's residence is provided in the application data sheet. Accordingly, applicants submit that the formality raised by the Examiner regarding the change in address in the declaration is moot under the USPTO guidelines. Furthermore, applicants submit that the change in address shown on the inventors' declaration is initialed by the inventor and the declaration is signed by the inventor. Accordingly, applicants question the grounds for the Examiner's presumption that this change of address was made after the inventor executed the declaration (that is, a revision to a declaration is proper so long as it is made prior to, or concurrently with, the inventor's execution; see MPEP 602.01, Rev. 2, May 2004). As to the Examiner's second objection, applicants submit that an inventors' declaration is not required to contain a reference to U.S. priority applications. See MPEP 602, Rev. 2, May 2004 and the CFR and patent statute provisions cited therein. Applicants further submit that the filing date of the priority application referenced in the inventor's declaration is provided both in the first paragraph of the specification and in the application data sheet. Accordingly, applicants respectfully request reconsideration and withdrawal of the Examiner's objection to the inventors' declaration.

In paragraph 5, the examiner has objected to the specification and requested correction of the address of the ATCC on page 30, line 9 and the revision of "Figure 3" to read "Figure 3 A-B" in the Brief Description of the Drawings. Applicants have amended the specification to make these revisions.

In paragraphs 6-7, the Examiner has rejected claims 52-55 as failing to comply with the written description requirement. The Examiner maintains that the specification does not disclose a kit comprising a nucleic acid encoding an agonist peptide. The Examiner further maintains that the specification does not disclose such a kit further containing an immunostimulatory molecule. The Examiner states, however, that the specification does discloses (1) a vector containing a nucleic acid encoding the sequences recited in claims 52-55, (2) a kit comprising an amino acid sequence encoded by these sequences (*e.g.*, "an agonist peptide") and (3) such a kit further comprising an immunosuppressive agent. Applicants respectfully traverse this rejection.

Even assuming solely for the sake of argument that the Examiner has correctly summarized the literal disclosure in the specification, literal disclosure is not the standard for determining whether a specification contains adequate written description for a claim. That is, the written description standard may satisfied, even though the specification does not provide the exact language recited in the claim. It is permissible under the law for written description to be provided by a (1) a combination of elements in the specification that would be necessarily apparent to the skilled artisan. See *Union Oil v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) (written description was adequately provided by combining different teachings in the specification where the specification did not disclose any embodiments corresponding to any of the claims at issue) (cited in MPEP 2163.06, page 2100-182, 1st col., Rev. 2, May 2004). Also, (2) written description may be provided by an advantage that is an inherent property of the invention. See MPEP 2163.07(a), page 2100-184, 1st col., Rev. 2, May 2004. Applicants respectfully submit that it is entirely proper under the law of written description to combine embodiments in the specification, as the skilled artisan would do in reading the specification, to conclude that the inventors were in possession of claims 52-55. Applicants submit that the skilled artisan would necessarily read the specification to disclose that the kits described therein could contain vectors comprising nucleic acid encoding the peptide agonists. In this regard, applicants respectfully direct the Examiner to page 20, lines 23-25, of the specification, which explicitly states that the "invention further provides vectors and plasmids comprising a DNA sequence encoding an agonist peptide." Applicants submit that one of skill in the art reading the disclosure of 1) kits containing peptide agonist in combination with 2) the disclosure that the peptide agonists may be expressed by vectors comprising DNA encoding them would necessarily conclude that the inventors were in possession of the kits containing nucleic acid encoding the sequences set forth in claims 52-55. Accordingly, applicants respectfully request reconsideration and withdrawal of the Examiner's rejection.

In paragraph 8, the Examiner has rejected claims 47-56 as failing to comply with the written description requirement. The Examiner maintains that the specification does not adequately describe the scope of the claimed genus which encompasses a substantial variety of subgenera including any nucleic acid molecule comprising any

nucleic acid sequence encoding polypeptide comprising one of SEQ ID NO: 2-5. The Examiner further maintains that claims 47-56 fail to comply with the written description requirement because the specification fails to provide sufficient relevant identifying characteristics of the genus and because the genus is highly variant and therefore, the Examiner maintains, the specification does not describe a representative number of species of the genus as broadly claimed. Applicants respectfully traverse this rejection. Applicants traverse this rejection on the following grounds.

First, applicants submit that the specification does disclose representative species of the claimed invention. The specification discloses embodiments for the claimed nucleic acid sequences on pages 19 to 20 of the specification. Second, the application does disclose an inherent description of vectors and nucleic acid flanking regions. See, for example, page 12 of the specification, lines 29-31, which discloses that the agonist peptide "may be obtained by recombinant DNA technology." The skilled artisan would inherently understand this description to include expression vectors containing the claimed nucleic acids. Expression vectors are well known to the skilled artisan and contain flanking nucleic acids that are well known including start codons and stop codons and other regions. Applicants respectfully submit that the claims are not limited to vectors for administration into the body nor are the claims limited to require that amino acids are expressed which flank the claimed SEQ ID NOs 2-5.

Second applicants respectfully traverse the examiner's rationale that the written description requirement is a high threshold because there is unpredictability in the art regarding the antigen processing of epitope amino acids and in particular there in unpredictability regarding the effect of regions that flank the epitope. Even, solely for the purpose of argument, if one assumes that the Examiner's technical points to be correct, the uncertainty stated by the Examiner regarding the effect of flanking regions on antigen processing does not make the claims unpredictable from a written description standpoint. The specification provides peptides of varying length and with varying flanking regions (e.g., vaccinia virus and avipox) which have been reported to produce CEA specific T cell responses, namely: CEA peptide, vaccinia CEA, avipox CEA, CAP1, and numerous CEA fragments, including the 9 mer CAP 1 peptide and a

177 CEA fragment containing the 9 mer CAP 1 peptide. See, e.g., pages 3-4 of the specification. Given this disclosure in the specification that CEA, CEA fragments and CAP1 provide a CEA specific T cell response and the further knowledge in the art of expression vectors for expressing the claimed sequences, applicants submit that the application does provide representative examples showing that the inventors were in possession of the claimed genus. Applicants respectfully submit that a patent application is not required to describe every detail and every species that fall within the claimed invention. See MPEP 2163, page 2100-173, 2d col., Rev. 2, May 2004 citing *In re Hayes*, 982 F.2d 1527 (Fed. Cir 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to disclose every detail of the invention.").

Furthermore, the Federal Circuit has recognized that the field of immunology is sufficiently advanced so that the description an antigen is sufficient to provide support for additional embodiments which are not disclosed in an application. See *Noelle v. Lederman*, 355 F.3d 1343, 1249 (Fed. Cir. 2004) ("as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen"). Applicants submit that this legal precedent is precisely analogous to the instant situation where the applicant has described the antigen and one of skill in the art is knowledgeable on how to express this antigen and how to construct vectors containing this antigen analogous to how one of skill in the art would know how to obtain an antibody directed to a disclosed antigen. Accordingly, applicants respectfully request reconsideration and withdrawal of the instant written description rejection.

In paragraph 9 of the application, the Examiner has rejected claims 47-56 as being non enabled because, for example, flanking sequences to SEQ ID NO: 2-5 are not disclosed and because, the Examiner maintains, the state of the art is unpredictable in the absence of appropriate evidence of whether the claimed nucleic acid molecules can be made. The Examiner further maintains that the specification provides no

evidence that peptides of SEQ ID NOs 2-5 (1) would be correctly processed and would bind to an MHC molecule when presented in a longer peptide of unknown length and flanked by amino acid sequence not present in the antigenic protein of origin and (2) would be recognized by CTL. Applicants respectively traverse this rejection for the reasons discussed above regarding the traversal of Examiner's rationale regarding the predictability in the art and the amount of experimentation required given the teachings of the instant specification. Furthermore, applicants submit that the combination of the claimed sequence CAP-6D included in the CEA sequence is currently in clinical trials, thus showing the enabling nature of the claimed invention. See Marshal et al., Journal of Clinical Oncology 23(4) (2005), a copy of which is attached. Accordingly, applicants respectfully request reconsideration and withdrawal of the instant enablement rejection.

In paragraphs 10-14, the Examiner has rejected certain claims over the prior art. This rejection is based on the Examiner's position that the claims are not entitled to a priority date prior to 12/3/03. The Examiner maintains that the rationale for this position is stated in paragraph 7 of the Office Action. Applicants respectfully request withdrawal and reconsideration of this rejection. Applicants submit that the rejection of paragraph 7 is traversed by this response.

Moreover, if this Examiner maintains that the rejection of paragraph 7, applicants respectfully traverse the instant rejection on the following grounds. A claim of priority is evaluated by comparing the instant specification filed 12/3/03 with the applications to which it claims priority. Applicants submit that the Examiner has not done this. The instant application is a continuation of parent application 09/529,121, filed June 13, 2000. This necessarily means that the instant application properly claims priority to at least June 13, 2000. This priority date antedates the primary reference cited by the Examiner. Accordingly, applicants respectfully request reconsideration and withdrawal of the Examiner's prior art rejections.

In paragraphs 15-17 of the Office Action, the Examiner has rejected certain claims under the doctrine of obviousness type double patenting. Applicants respectfully request that this rejection be held in abeyance until allowable subject matter has been determined, as is permitted under the relevant USPTO rules.

In paragraph 18 of the Office Action, the Examiner has noted that the USPTO normally will not institute an interference between commonly owned applications. Applicants acknowledge this procedure and respectfully request that this issue be held in abeyance until otherwise allowable subject matter has been determined, as is permitted under the relevant USPTO rules.

Conclusion

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of the instant rejections. The Examiner is invited to contact the undersigned if any questions arise regarding this response.

Respectfully submitted,

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